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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,943	03/08/2000	KUBER T. SAMPATH	CIBT-P01-570	7342
28120	7590	07/26/2004	EXAMINER	
ROPE & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/423,943

**Applicant(s)**

SAMPATH ET AL.

**Examiner**

Janet L. Andres

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,5-29 and 76 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,29 and 76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6, 8-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 6 May 2004 is acknowledged. Claims 1, 3, 5-29, and 76 are pending in this office action. Claims 5, 7, 29, and 76 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Claim Rejections Withdrawn***

2. The rejection of claims 1, 3, 6, and 8-28 under 35 U.S.C. 112, second paragraph, is withdrawn since the term "analog" merely refers to an agent to be tested.

### ***Claim Rejections Maintained***

3. The rejection of claims 1, 6, 12-15, 20, and 23-28 under 35 U.S.C. 103(a) as unpatentable over WO 93/04692 in view of the '706 patent is maintained for reasons of record in the office action of 23 December 2003.

Applicant argues that WO 93/04692 describes a method of protection of tissue, not of inducing new formation. Applicant further argues that the '706 patent teaches away from evaluating morphogens because it teaches that OP-1 is downregulated during renal failure.

Applicant's arguments have been fully considered but have not been found to be persuasive. On p. 9, lines 25-35, and p. 10, lines 1-10, WO 93/04692 does teach tissue repair is part of what is encompassed by the concept of protection. On p. 35, lines 22-33, it is again stated that protection includes "regenerating the damaged tissue". Similarly, on p. 40, lines 33-36, it is stated that the "morphogens further enhance the viability of the damaged tissue and/or organs by stimulating the regeneration of the damaged tissue". Administration after the onset of injury is taught in example 3, pp. 69-71 and in example 14, pp. 92-93. Thus, while prophylaxis may be

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the preferred embodiment, the methods of WO 93/04692 clearly encompass tissue repair. That the '706 patent teaches that OP-1 is downregulated during renal failure does not teach away from its use in regeneration. OP-1 is well known as a morphogen and many factors other than the 'logic' provided by the specification of the '706 patent are involved in regulation.

4. The rejection of claims 3, 6, and 8-28 under 35 U.S.C. 103(a) as unpatentable over WO 93/04692 in view of the '706 patent and Benet et al. is maintained for reasons of record in the office action of 23 December 2003.

Applicant argues as above, that WO 93/04962 does not teach new tissue formation. For the reasons set forth above, this argument has not been found to be persuasive.

NO CLAIM IS ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
22 July 2004



**JANET ANDRES**  
**PRIMARY EXAMINER**